



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0245; FRL-9345-1]

RIN 2070-ZA16

Methyl Bromide; Proposed Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish a tolerance for residues of methyl bromide in or on cotton, undelinted seed under the Federal Food, Drug, and Cosmetic Act (FFDCA) because there is a need for imported undelinted cottonseed for use as feed for dairy cattle in the United States. This imported cottonseed has become necessary because cottonseed is a critical part of the dairy cattle diet and the 2011 U.S. cotton crop was significantly below average due to severe drought conditions in Texas.

DATES: Comments must be received on or before [*insert date 60 days after publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2012-0245, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2012-0245. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your

comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Kimberly Nesci, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: (703) 308-8059; email address: neski.kimberly@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified. Comments not timely-filed will not be considered in EPA's decision on this proposal or in any subsequent proceedings in this rulemaking.

II. This Proposal

EPA on its own initiative, under FFDCA section 408(e), 21 U.S.C. 346a(e), is proposing to establish a tolerance for residues of the fumigant methyl bromide, in or on cotton, undelinted seed at 150 parts per million (ppm) in newly proposed 40 CFR 180.124. The Animal and Plant Health Inspection Service, an agency of the United

States Department of Agriculture (USDA-APHIS), supports EPA's proposal to establish this tolerance.

Undelinted cottonseed, also known as fuzzy cottonseed, needs to be imported into the United States for use as feed for dairy cattle in the United States. Cottonseed is a critical part of the dairy cattle diet because it is high in protein, energy, and fiber. In 2011, the size of the U.S. cotton crop was significantly below average due to severe drought conditions in Texas, the leading cotton producing state in the United States. As a result, U.S. cottonseed has been in short supply since the November 2011 harvest causing hardship for U.S. dairy cattle farmers.

The USDA-APHIS has, in the past, pursuant to its authorities from the Plant Protection Act (PPA, as amended, 7 U.S.C. 7701 et seq.), required imported cottonseed to be fumigated as a condition of entry into the United States. APHIS evaluated the use of methyl bromide for such fumigation and has determined through efficacy studies that methyl bromide does effectively mitigate potential pests of concern such as *Fusarium oxysporum* f. sp. *vasinfectum* strains Boggabilla (VCG01112) and Cecil Plains (VCG01111) that imported undelinted cottonseed could harbor. These *Fusarium* strains are not known to occur in the United States. *Fusarium oxysporum* f. sp. *vasinfectum* causes Fusarium wilt of cotton and, if introduced, these foreign strains could cause significant losses to U.S. cotton crops. The PPA authorizes the Secretary of Agriculture (who has delegated this authority to APHIS) to facilitate imports of agricultural commodities that pose a risk of harboring plant pests, among other pests, in ways that will reduce the risk of dissemination of plant pests that could constitute a threat to crops and other plants or plant products and burden interstate or foreign commerce. The

Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, noxious weed, or article if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction of a plant pest into the United States or the dissemination of a plant pest within the United States.

As a feed commodity, imported cottonseed that has been fumigated with methyl bromide requires a tolerance. Without a tolerance or exemption, food or feed containing pesticide residues is considered to be unsafe and therefore “adulterated” under section 402(a) of FFDCA, 21 U.S.C. 342(a). Such food or feed may not be distributed in interstate commerce (21 U.S.C. 331(a)).

III. Determination of Safety and Exposure

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Given the characteristics of methyl bromide, EPA concludes that the use of methyl bromide on cottonseed will result in detectable residues on the cottonseed itself.

Although the Agency does not have controlled fumigation trial data for this cottonseed use, EPA has received such data for numerous other related commodities and use patterns. The data that would be most representative of potential residues in/on cottonseed are from methyl bromide trials with tree nuts because commodities with higher fat content, such as nuts and oils, tend to have higher residues. EPA is proposing a tolerance level of 150 parts per million (ppm), which is based on the highest residue found in tree nuts 24 hours after fumigation (138 ppm). Dissipation studies indicated that residues dissipate relatively quickly, which is consistent with the high vapor pressure of methyl bromide. Despite the tendency for rapid dissipation shown in numerous studies, the Agency believes there is still the potential for quantifiable residues in the imported cottonseed. However, residues are likely to be much less than the proposed tolerance level.

EPA further concludes that the use of methyl bromide to fumigate imported cottonseed will not result in any human dietary exposure to methyl bromide residues. There are two potential human dietary exposure pathways from treated cottonseed: cottonseed oil, an edible commodity produced from cottonseed, and livestock commodities from livestock fed treated cottonseed. Cottonseed itself is not consumed by humans, nor is it used to produce any other edible commodity because unrefined cottonseed and cottonseed meal contains a naturally occurring compound that is toxic to humans, gossypol.

Cottonseed will be imported for the purpose of feeding dairy cattle. There is no reasonable expectation of finite residues of methyl bromide in livestock commodities from the use of methyl bromide to fumigate cottonseed. Methyl bromide residues in/on

feed items are likely to significantly dissipate during storage due to the volatile nature of methyl bromide. Should there be methyl bromide residues remaining, the methyl bromide would likely undergo considerable changes in the digestive system of livestock. Methyl bromide is an alkylating agent and will probably undergo chemical reactions with the contents of the gut. These chemical reactions break down the compound into a bromide ion and a methyl group; thus, there will be no absorption of methyl bromide into the edible tissues of livestock. Further, methyl bromide has a very low octanol-water co-efficient. Octanol-water co-efficient values measure the tendency for a chemical to partition into organic vs. aqueous environments, and is therefore commonly used to predict the likelihood for partitioning into fatty tissue where xenobiotics are more likely to persist. Chemicals that tend to bioaccumulate tend to have orders of magnitude higher octanol-water co-efficient values than methyl bromide. And, although methyl bromide tends to be lipid soluble, the low octanol-water co-efficient value overwhelms this chemical characteristic. For these reasons, EPA does not believe there will be transfer of methyl bromide residues into the edible tissues of livestock. In its Reregistration Eligibility Decision document for methyl bromide, EPA also determined that no livestock commodity tolerances for methyl bromide are needed under 40 CFR 180.6(a)(3) because there is no reasonable expectation of finite methyl bromide residues in livestock commodities. Any inorganic bromide residues on livestock feeding items resulting from fumigation of cottonseed with methyl bromide are covered by existing inorganic bromide tolerances at 40 CFR 180.124.

Even if the imported cottonseed were to be diverted to cottonseed oil production, there will be no human exposure to methyl bromide in the cottonseed oil. In producing

oil from cottonseed, the oil is removed by mechanical high pressure screw, by solvent extraction, or a combination of the two processes. Under either procedure, the seed kernels are first rolled into flakes and heated in a cooker or conditioner to reduce moisture. Once the oil is extracted, it is refined by adding sodium hydroxide that removes impurities and soapstock from the oil. Most cottonseed oil is bleached to remove coloring agents and is then filtered. Finally, it is deodorized with steam under a partial vacuum to remove any off flavors. Bromide ion will be removed from the oil during the final clean-up steps because the bromide ion is water soluble and will be washed away during the sodium hydroxide refining procedure. See also Docket EPA-HQ-OPP-2006-0766 document number 0022 for further information on cottonseed processing. Because methyl bromide is a gas at room temperature, the heating procedures in cottonseed oil processing will dissipate all methyl bromide residues from the seed and oil. Cottonseed oil produced from cottonseed fumigated with methyl bromide would not contain residues of methyl bromide.

Accordingly, EPA has determined that there would be no human dietary exposure to methyl bromide from the use of methyl bromide to fumigate cottonseed. If meat, milk, or cottonseed oil were imported rather than the cottonseeds themselves, no tolerance would be necessary. Because there will be no human dietary exposure to the methyl bromide in cottonseeds, EPA concludes that a methyl bromide tolerance in cottonseed, at the level proposed, will be safe for the general population, including infants and children.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical method, the head-space procedure of King et al. is available for enforcement of methyl bromide tolerances. Samples are blended with water at high speed in air-tight jars for 5 minutes. After 15 minutes, the partitioned gas phase is sampled and analyzed by gas chromatography with electron capture detection (GC/EC). See the February 22, 2002, Residue Chemistry Chapter for the methyl bromide RED available in Docket EPA-HQ-OPP-2005-0123.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for methyl bromide on cottonseed.

V. Conclusion

A tolerance is proposed for residues of methyl bromide in cottonseed at 150 ppm based on the finding that there would be no human dietary exposure to methyl bromide from treated cottonseed and no exposure to children.

VI. Statutory and Executive Order Reviews

EPA, at its own initiative, proposes to establish a tolerance under FFDCA section 408(d). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “*Regulatory Planning and Review*” (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, entitled “*Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*” (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled “*Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*” (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled “*Protection of Children from Environmental Health Risks and Safety Risks*” (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Pursuant to the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this proposed action will not have significant negative economic impact on a substantial number of small entities. Establishing a pesticide tolerance or exemption from the requirement of a pesticide

tolerance is, in effect, the removal of a regulatory restriction on pesticide residues in food and thus such an action will not have any negative economic impact on any entities, including small entities. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “*Federalism*” (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any “tribal implications” as described in Executive Order 13175, entitled “*Consultation and Coordination with Indian Tribal Governments*” (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive order to include regulations that have “substantial direct effects on one or more

Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 2, 2012.

Steve Bradbury,

Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.124 to subpart C to read as follows:

§ 180.124 Methyl bromide; tolerance for residues.

(a) *General.* A tolerance is established for residues of the fumigant methyl bromide, including metabolites and degradates, in or on the commodity in the table below. Compliance with the tolerance level specified below is to be determined by measuring only methyl bromide.

Commodity	Parts per million
Cotton, undelinted seed	150

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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